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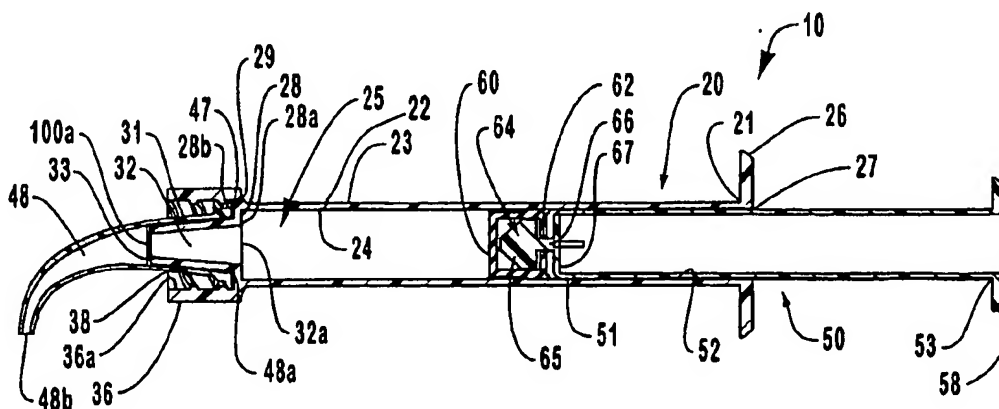
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(54) Title: SYRINGE APPARATUS WITH A RUPTURABLE MEMBRANE AND RELATED METHODS



(57) Abstract: A syringe (10) is provided for delivering compositions. The syringe (10) has a delivery tip (40) coupled to a hollow elongated barrel (20) with a rupturable membrane (100a) positioned between the barrel (20) and the delivery tip (40). The rupturable membrane (100a) prevents the flow of a composition until pressure is exerted against the composition so that the composition is pushed against the rupturable membrane (100a) with a force sufficient to rupture the rupturable membrane (100a). After the membrane (100a) has been ruptured, then the composition may flow out of a chamber (24) of the barrel (20) via a flow opening of the chamber (24) and into the conduit (48) of the delivery tip (40). The syringe (10) also has a plunger (50) engaged by the barrel (20).

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## SYRINGE APPARATUS WITH A RUPTURABLE MEMBRANE AND RELATED METHODS

### BACKGROUND OF THE INVENTION

#### 1. The Field of the Invention

The present invention relates to a syringe apparatus for dispensing compositions. More particularly, the present invention is directed to syringes that have a rupturable membrane.

#### 2. The Relevant Technology

Many syringes are presently sold prefilled with composition so that the syringes are ready for use. Many of the types of compositions that are distributed in such preloaded syringes are prone to evaporation or to reacting when exposed to elements such as light, humidity or air. Accordingly, it is necessary to protect the contents held in preloaded syringes from such elements.

One approach is to use a plastic cover such as the vinyl covers sold by Ultradent Products, Inc. as TipSoc™ covers. An example of such a cover is shown in Figure 1A at 70 placed on delivery tip 40. Another approach is to seal the syringe with a cap such as the luer lock caps sold by Ultradent Products, Inc. An example of such a cap is shown at 80 in Figures 1B-1C. Such a cap is replaced with a syringe tip such as syringe tip 40 when delivery of the contents from syringe 10 is desired.

A disadvantage of using cover 70 or cap 80 is that they must be removed before the syringe can be used. Additionally, if cap 80 is used then syringe tip 40 must also be attached after cap 80 is removed. Use of cover 70 or cap 80 also increases the cost of the syringe.

In conclusion, a syringe is needed which enables a user to deliver a composition from a preloaded syringe without requiring the removal of a protective cover or cap. A syringe is also needed which enables a user to deliver a composition from a preloaded syringe more efficiently and in a more cost effective manner.

### BRIEF SUMMARY OF THE INVENTION

The present invention provides a novel syringe apparatus including a syringe and a rupturable membrane held between the barrel of the syringe and the delivery tip.

By using the membranes of the present invention, it is possible to store materials in a syringe until the materials are ready for use without requiring the user to remove a cap in order to mix fresh, separated materials.

The rupturable membrane is positioned between the barrel and the delivery tip. The rupturable membrane is positioned such that it prevents the flow of a composition held in a chamber of the barrel until pressure is exerted against the composition so that the composition is pushed against the rupturable membrane with a force sufficient to rupture the rupturable membrane. After the membrane has been ruptured, then the composition may flow out of the chamber of the barrel via a flow opening of the chamber and into a conduit of the delivery tip via a conduit inlet.

The above described syringe and method of use provides several advantages and improvements over the prior art. The syringes can be used with any composition, however, such plungers are particularly useful with dental compositions.

These and other features and advantages of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

### **BRIEF DESCRIPTION OF THE DRAWINGS**

In order that the manner in which the above-recited and other advantages of the invention are obtained will be understood, a more particular description of the invention briefly described above will be rendered by reference to a specific embodiment thereof which is illustrated in the appended drawings. Understanding that these drawings depict only a typical embodiment of the invention and are not therefore to be considered to be limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings as listed hereinbelow.

Figure 1A is a perspective view of a syringe 10 without a rupturable membrane and using a cover on a delivery tip to protect the contents of the syringe.

Figure 1B is perspective view of a syringe 10 without a rupturable membrane and using a cap in place of a delivery tip to protect the contents of the syringe.

Figure 1C is a cross-sectional view of the syringe 10 shown in Figure 1B.

Figure 2A is an exploded perspective view of a syringe 10, a rupturable membrane 100a and a delivery tip 40.

Figure 2B is a cross-sectional view of the syringe 10, rupturable membrane 100a and delivery tip 40 as shown in Figure 2A.

Figure 2C is a perspective view of a syringe 10 and delivery tip 40 having a rupturable membrane positioned there between as shown in Figure 2A. Syringe 10 is preloaded with a composition and the plunger positioned to rupture the membrane in order to initially express the composition from the syringe.

Figure 3A is an enlarged exploded perspective view of a preshaped rupturable membrane 100b adapted to fit exit tube 30. Figure 3A also shows barrel 20 and delivery tip 40.

Figure 3B is an enlarged partial cross-sectional view corresponding with Figure 3A.

Figure 3C is an enlarged cross-sectional view corresponding with Figure 3A.

Figure 3D is an enlarged cross-sectional view showing barrel 20 and delivery tip 40 with a rupturable membrane 100b' there between having a drape portion positioned between conduit 48 and sidewall 31.

Figure 4 is an enlarged cross-sectional view showing rupturable membrane 100c over exit tube outlet 32b and positioned between barrel 20 and delivery tip 40'.

Figure 5A is an enlarged exploded cross-sectional view of delivery tip 140, rupturable membrane 100d and barrel 20' without an exit tube.

Figure 5B is an enlarged cross-sectional view of delivery tip 140, rupturable membrane 100d and barrel 20' without an exit tube as shown in Figure 5A after the rupturable membrane is positioned between delivery tip 40' and barrel 20'.

Figure 5C is an enlarged exploded cross-sectional view of delivery tip 240, preshaped rupturable membrane 100e and barrel 20". Note that barrel 20" does not have an exit tube or a radial extension.

Figure 5D is an enlarged cross-sectional view of delivery tip 40", preshaped rupturable membrane 100e and barrel 20" as shown in Figure 5C after the rupturable membrane is positioned between delivery tip 240 and barrel 20".

#### **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

The present invention is directed to methods and apparatus for dispensing compositions. More particularly, the present invention is directed to a syringe apparatus which enables a user to deliver a preloaded composition without requiring the removal of a protective cover or cap. The syringe apparatus includes a syringe with a rupturable membrane held between a delivery tip and a barrel.

Many compositions that are distributed in preloaded syringes are prone to evaporation or to reacting when exposed to elements such as light, humidity or air.

Accordingly, it is necessary to protect such composition when held in preloaded syringes from such elements. Examples of compositions which are typically preloaded from in syringes include dental compositions such as dental cements, restorative compositions and root canal sealers. The rupturable membrane as used in the present invention seals such compositions within the syringe to prevent evaporation or undesired reactions.

The rupturable membrane is identified in the accompanying drawings at 100a, 100b, 100b', 100c, 100d and 100e. Since rupturable membranes 100a, 100b, 100b', 100c, 100d and 100e are all different embodiments of the rupturable membrane, reference is generically made herein to rupturable membrane 100 unless specific reference is being made to the particular embodiment of the rupturable membrane.

Before describing in detail the location of rupturable membrane 100 between delivery tip 40 and barrel 20, the components of syringe 10 and their configurations are set forth in detail to appreciate the use of rupturable membrane 100. Syringe 10 is an example of a widely used conventional syringe. The primary components of syringe 10 include a barrel 20 and a plunger 50 which is slidably engaged in barrel 20.

As shown in Figure 2A and 2B, plunger 50 has pushing handle 58 opposite a cylindrically shaped sealing gasket 60. Gasket 60 is made of a soft, compressible, sealing material, such as rubber, which allows the exterior surface of gasket 60 to seal against barrel 20 to ensure that the fluids held within barrel 20 do not leak.

Barrel 20 has a top grasping end 21 opposite a bottom end 29 with a substantially cylindrical sidewall 22 extending therebetween. Sidewall 22 has an exterior surface 23 and an interior surface 24. Interior surface 24 defines a substantially cylindrical or tubular chamber 25 for holding a composition. Chambers such as chamber 25 of barrel 20 are typically configured to hold about 1.2 cc of liquid.

Barrel 20 has a grasping handle 26 which is an annular flange extending radially outward from sidewall 22 at top grasping end 21 of barrel 20. Grasping handle 26 is centrally located around access opening 27 which has the same diameter as the interior surface 24 of chamber 25.

Barrel 20 has a radial extension 28 extending integrally from sidewall 22 at bottom end 29 inward to define an exit port 32. Interior surface 28a of radial extension 28 acts as a stop for plunger 50 as plunger 50 is depressed. Exterior surface 28b of radial extension 28 engages delivery tip 40, as described hereinbelow.

As shown in Figure 2A, barrel 20 has an exit tube 30 located at bottom end 29. Exit tube 30 is shown as having a cone shape for insertion into conduit 48 of delivery tip

40. The exit tube may, however, also have a cylindrical configuration or any other suitable configuration.

Exit tube 30 has a sidewall 31 and a channel 33 that extends through exit tube 30. Barrel 20 has an exit port 32a defined by radial extension 28 that is the opening into channel 32. Exit port 32a enables channel 32 to communicate with chamber 25. Note that channel 32 is the interior surface of tapered exit tube 30. Channel 32 extends through tapered exit tube 30 and terminates at exit tube outlet 32b located opposite exit port 32a.

Note that in syringe 10', described in reference below to Figures 5A-5B, syringe 10' has no exit tube so exit port 32a' is defined only by radial extension 28. Note also that in syringe 10" described below in reference to Figures 5C has no exit tube 30 and no radial extension 28 so exit port 32a" is merely defined by the interior surface 24 of chamber 25. Whether the composition held in the chamber of the barrel flows out an exit tube outlet such as outlet 32b, out of exit port 32a' as shown in Figures 5A-5B or out of an exit port 32a" as shown in Figure 5C, the composition flows out of a flow opening. Such flow openings are located at the bottom end of the barrel for enabling the composition held in the chamber to exit the chamber.

Surrounding exit tube 30 is an attachment sleeve 36. Attachment sleeve 36 has an interior surface 36a with engagement threads 38 positioned thereon. A delivery tip 40, shown in Figures 2B and 2C, may be selectively attached to barrel 20 by coupling with threads 38. A variety of tips are available which may be attached such that chamber 25 is in fluid communication with the tip for guided delivery of the composition to a desired location.

Delivery tip 40 is configured to selectively attach in fluid communication with exit tube 30. To accomplish this end, tip 40 has a threaded end 42 for engagement with threads 38 of attachment sleeve 36. More particularly, a flange 42 is located at coupling end 41 that has threads 43. In alternative embodiments, structures other than threads may be used to attach different sizes and/or shapes of tips.

Opposite coupling end 41 is a delivery end 45 with a body 44 extending therebetween. Body 44 has a hub portion 44a and a spout portion 44b. Spout portion 44b is configured for guiding delivery of the composition to a desired location. Spout portion 44b is preferably flexible and angled. Fins 46 extend from hub portion 44a which are adapted for being gripped to twist delivery tip 40 so that threads 43 engage threads 38 and lock delivery tip 40 into position.

While delivery tip 40 is shown having a curved spout portion 44b, the delivery tip may have many different configurations depending on the type and intended use of the composition. For example, instead of an integral spout portion, the spout portion may be a metal cannula as shown in Figures 5A-5B at 44b'. The delivery tip 140 shown in Figures 5A-5B is described in detail below and is similar to the tips sold by Ultradent Products, Inc. as Endo-Eze® Irrigator Tips. The spout portion may also be straight such as the tips sold by Ultradent Products, Inc. as Capillary™ Tips. Delivery tip 240 shown in Figures 5c-5D has such a straight portion 44b".

Delivery tip 40 has a top surface 47 that engages receiving surface 28b of barrel 20. A conduit 48 extends through delivery tip 40 having a conduit inlet 48a and a conduit outlet 48b. The conduit inlet 48a is defined by top surface 47 and is opposite the conduit outlet 48b. The conduit outlet 48b is located at delivery end 45. Top surface 47 extends to flange 42.

The plunger may have any suitable configuration. Although, the syringe apparatus of the present invention may be utilized with any plunger, plunger 50 is described in detail to provide a complete example of a plunger. Plunger 50 has a distal lead end 51 opposite from a proximal pushing end 53 with a stem 52 extending therebetween. Radially extending outward at pushing end 53 is an annular pushing handle 58 used in advancing plunger 50. Plunger 50 is sized to be slidably received within chamber 25 through access opening 27 at top grasping end 21. Plunger 50 has a length that permits it to be advanced to bottom end 29 such that a small portion of plunger 50 remains extending beyond access opening 27. Figure 2C depicts a loaded syringe with only gasket 60 and a portion of stem 52 in chamber 25 of barrel 20. In use, plunger 50 is depressed into chamber 25 until rupturable membrane 100 is ruptured. Plunger 50 is pushed further and further into chamber 25 until gasket 60 contacts radial extension 28 to stop the depression of plunger 50.

Cylindrically shaped sealing gasket 60 is positioned at lead end 51 of plunger 50. More particularly, gasket 60 is coupled to stem 52 via a gasket holder as shown in Figure 2B at 64. As indicated above, gasket 60 is made of a soft, compressible, sealing material, such as rubber, which allows the exterior surface of gasket 60 to seal against interior surface 24 of chamber 25 as plunger 50 is advanced within chamber 25 or selectively slid down to bottom end 29.

Gasket holder 64 has a post 66 with a head element 65 integrally extending at one end and a base 67 integrally extending from the other end. Head element 65 and post 66 are inserted into an opening 62 of gasket 60 which expands such that head element 65

can be inserted therein and then elastically return to its original size such that head element 65 is removably held in gasket 60. Base 67 is connected to stem 52 to hold gasket holder 64 in position.

Figures 2A-2C depict rupturable membrane 100a as being disc shaped until being positioned over 32b engaged for delivery tip 40 is positioned on exit tube 30. After threads 38 of sleeve 36 and threads 43 delivery tip 40 have been engaged and delivery tip has been tightened into position, the rupturable membrane is held in place. More particularly, rupturable membrane is mounted between conduit 48 of delivery tip 40 and sidewall 31 of exit tube 30. The action of conduit 48 against sidewall 31 preferably stretches rupturable membrane 100 so that it is drawn tight over exit tube outlet 32b.

In the embodiment of Figure 2A-2C, membrane 100 acts as a seal over exit tube outlet 32b to prevent material from being expressed prematurely from chamber 25 of syringe 20. However, upon advancing plunger 50 into barrel 20 such that the material in chamber 25 of barrel 20 is advanced through channel 32, membrane 100 can rupture, thereby allowing material to be expressed through channel 32 and then through conduit 48 of delivery tip 40. Thus, the need for covers and caps is eliminated. Additional examples of membranes are shown at 100b in Figure 3A-C, at 100b' in Figure 3D, at 100c in Figure 4, and at 100d in Figures 5A-5C.

Figure 3A-3C shows a rupturable membrane 100b which has been preshaped to fit onto exit tube 30. More particularly, rupturable membrane has a flat portion or flat disc portion 102 and a drape portion 104 integrally hanging therefrom with a frustoconical shape adapted to the cone shape of the sidewalls 31 of exit tube 30. While drape portion 104 has a frustoconical shape, it can have any shape, such as a cylindrical shape, which corresponds with that of the sidewalls of exit tube 30. Drape portion is long enough to extend down exit tube 30 and reach the exterior surface 28b of radial extension 28. A flange portion 106 extends radially outward from drape portion 104 and is positioned over exterior surface 28b of radial extension 28. Flange portion 106 is held between top surface 47 of delivery tip and receiving surface 28b of barrel 20 to form a seal. A seal is also formed between conduit 48 of delivery tip 40 and sidewall 31 of exit tube 30. Rupturable membrane 100b accordingly forms a very secure seal against flow of the material held in chamber 25 until plunger 50 is depressed and against ingress of elements into chamber 25 through exit port 32a.

The seal formed between by the pressure of conduit 48 of delivery tip 40 and sidewall 31 of exit tube 30 against drape portion 104 is typically adequate to prevent the flow of material held in chamber 25 until plunger 50 is depressed and to prevent ingress



of elements into chamber 25 through exit port 32a. Accordingly, rupturable membrane 100b' is shown in Figure 3D without a flange portion and a shorter drape portion 104' than drape portion 104. While the drape portion may extend all the way to exterior surface 28b of radial extension 28 without a flange portion, it may also have a very short length so that it extends just barely beyond exit tube outlet 32b. More particularly, since a seal can be formed by the pressure of conduit 48 and sidewall 31 against drape portion 104' at any appropriate location between conduit 48 and sidewall 31 as shown in Figure 3D, the drape portion can have any appropriate length.

Rupturable membrane 100b' may be preshaped and then held in position with or without stretching. Rupturable membrane 100b' may also be initially positioned over exit tube outlet 32b and the stretched into place as it is sandwiched between conduit 48 and sidewall 31. Similarly, the other rupturable membranes which are shown herein after being positioned or sandwiched may be either stretched into that particular configuration or may be preshaped and then positioned with or without stretching.

Figure 4 depicts a rupturable membrane 100c which has been preshaped to fit over only exit tube outlet 32b without extending down the sidewall 31 of exit tube. More particularly, rupturable membrane 100c has no portion which drapes beyond exit tube outlet 32b, it is merely attached to rim 33. Rupturable membrane may be initially placed on rim 33 and held in place by relying only on gravity. Additionally, rupturable membrane 100c may have an inherent tackiness which enables it to remain in place until the delivery tip 40' is positioned. The tackiness or stickiness also assists it to remain in position once stretched. Rupturable membrane 100c may also be mounted with an adhesive onto rim 33. Delivery tip 40' has a radial engagement surface 49 in conduit 48 configured to mate with rim 33 to sandwich rupturable membrane 100c. Radial engagement surface 49 is essentially a radial constriction in conduit 48 positioned at a length to securely contact rim 33 when delivery tip 40' is tightened onto sleeve 36 of barrel 30.

It is generally not necessary to preshape rupturable membranes that are capable of stretching as they can stretch into a desired position. In some instances, it may be easier to initially place preshaped rupturable membranes. However, as shown herein, some configurations enable flat rupturable membranes to be more easily initially positioned. Flat rupturable membranes are also preferably capable of stretching as needed so that as the membranes are sandwiches, they can stretch and conform so that a seal is formed. In many configurations, the seal is not formed until the sandwiching occurs or until stretched by the pressure of being sandwiched. In any event, membranes

which are stretchable are preferred as their ability to deform and conform to varying structural configurations enables them to be so adaptable that they can be used with ease.

Figures 5A-5B depicts a syringe 10' without an exit tube 30. The rupturable membrane 100d is a disc before being mounted between delivery tip 140 and the exterior surface 28b of radial extension 28. After being compressed between flange 42 of delivery tip 140 and radial extension exterior surface 28b of plunger 20, rupturable membrane essentially has a flat disc portion 102 and an integral draped portion 104. Disc portion 102 is pressed between top surface 47 and exterior surface 28b. Draped portion 104 of rupturable membrane 100d is pressed between flange 42 and interior surface 36; more particularly, draped portion 104 is pressed between threads 43 and 38.

Rupturable membrane 100d is preferably positioned over top surface 47 of delivery tip 140 before the delivery tip is inserted into sleeve 36 to be locked to barrel 20. Rupturable membrane can also be prepositioned over exterior surface 28b with a diameter corresponding essentially to that of interior surface 36a of sleeve or larger. If the rupturable membrane is prepositioned over exterior surface 28b with a diameter corresponding to essentially that of the interior surface 36a then it will form a seal primarily due to the pressure between exterior surface 28b and top surface 47 of delivery tip 140. If the rupturable membrane is larger, however, then it will also form a seal between threads 43 of delivery tip 140 and threads 38 of sleeve 36. Of course, a rupturable membrane can also be used with syringe 10' that is a preformed rupturable membrane such as preformed rupturable membranes 100b and 100b'. The preformed rupturable membrane may be configured to be draped over top surface 47 and flange 42 of delivery tip 140 or tucked into sleeve 36 over exit port 32a.

Figure 5C depicts a syringe 10" without an exit tube 30 and without a radial extension 28. Rupturable membrane 100e is first mounted on top surface 47 of delivery tip 240 in a preformed configuration, however, a disc shaped rupturable membrane can also be used as described above in reference to Figures 5A-5B. Insertion of delivery tip 240 into sleeve 36 compresses rupturable membrane 100d such that its flat disc portion 102 extends over top surface 47 and is in contact with the composition held in chamber 25 at exit port 32a". The disc portion 102 of rupturable membrane is not pressed in syringe 10". However, draped portion 104 of rupturable membrane 100d is pressed between flange 42 and interior surface 36; more particularly, draped portion 104 is pressed between threads 43 and 38.

As described above, membranes 100 can be merely positioned in a manner such that the compression of a portion the delivery tip against a portion of the barrel ensures

that a seal is formed. However, membranes 100 are preferably mounted by being stretched over an opening. Membrane 100 can be configured to be self-sealing when stretched into position without additional mechanisms or adhesives. As mentioned above, an adhesive can be employed, however, adhesive are generally not necessary. As yet another option, the membrane may be wrapped onto itself to form a seal, such as by forming the membrane around the entire delivery tip, and gathering the ends of the membrane together so as to stick against each other.

Membranes 100 are preferably comprised of a self-sealing, stretchable, rupturable film which is mounted by stretching the membrane over an opening of either the delivery tip or an opening of the barrel. Examples of such self-sealing, stretchable films include thin films comprising: (i) polyolefins and paraffin wax, (ii) rubbers, waxes and resins, (iii) a paraffin-wax-coated packaging film or (iv) a plasticised polyethylene film. Commercially available examples of useful rupturable membranes include (i) PARAFILM® "M" laboratory film available from Pechiney Corporation of Greenwich, Connecticut 06836, formerly, American National Can Company, and (ii) NESCOFILM™, available from Azwell, Inc., of Osaka, Japan.

However, a variety of different rupturable membranes may be employed so long as the membrane is capable of forming a seal over an opening of either the barrel or the delivery tip and rupturing from pressure applied by depression of the plunger into the chamber of the barrel. Such membranes may be mounted through self-sealing by stretching it into position on either the barrel or the delivery tip before coupling the barrel and delivery tip together, through the use of an adhesive, by mechanical methods such as sandwiching it between the barrel and the delivery tip, and by any other methods known to those skilled in the art.

Each membrane disclosed herein prevents the flow of a composition held in chamber 25 until plunger 50 is depressed and also prevents ingress of elements into chamber 25 through exit port 32a. Consequently membrane 100 is an example of a rupturable means for sealing an opening in a plunger to prevent ingress of elements into the chamber and to prevent the flow of the composition out of the chamber through the opening.

Although, the membranes are either shown as being either disk-shaped or as being preformed to have a flat portion and a drape portion, the membranes of the present invention can have any suitable shape. For example, the membranes may be an oval-shaped membrane, a square-shaped membrane, and a variety of other shapes and configurations.

Rupturable membranes such as those disclosed herein may be used in many various devices in addition to syringes.

Barrels 20, 20' and 20" are only examples of preferred barrel configurations. The barrels disclosed herein are examples of barrel means for holding a composition. Note also that the plungers disclosed herein are examples of plunger means for advancing the composition positioned within the barrel through the flow opening such as the exit port at the bottom end of the barrel.

The delivery tips 40, 40', 140 and 240 disclosed herein are also just examples of preferred delivery tip configurations. Many other delivery tip configurations are widely known and used. These delivery tips are examples of means for delivering the composition from the barrel means out of the syringe.

Additionally, the rupturable membranes disclosed herein are examples of preferred configurations. The disclosed materials used to form the rupturable membranes are also exemplary. Such rupturable membranes are examples of means for rupturable sealing of the composition held within the barrel means to prevent the composition from flowing out of the barrel means until pressure is exerted against the composition so that the composition is pushed against the rupturable sealing means with a force sufficient to rupture the rupturable sealing means.

The use of rupturable membranes as disclosed herein provides examples of methods for sealing a composition within a chamber until sufficient pressure is applied against rupturable membrane to rupture the membrane and to enable the composition to flow out of the chamber. While the rupturable membranes are shown in use with syringes, the rupturable membranes can be used with many other devices which hold a composition to prevent the flow of the composition out of the device and to prevent the ingress of elements such as moisture, air or light.

It will be appreciated that the present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive, and the scope of the invention is indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A syringe apparatus for dispensing a composition, the syringe comprising:
  - (a) barrel means for holding a composition, the barrel means having a flow opening located at a bottom end of the barrel means to enable the composition held in the chamber to exit the chamber;
  - (b) means for delivering the composition from the barrel means out of the syringe, the delivery means being coupled to the bottom end of the barrel to receive the composition from the barrel means; and
  - (c) means for rupturable sealing of the composition held within the barrel means to prevent the composition from flowing out of the barrel means until pressure is exerted against the composition so that the composition is pushed against the rupturable sealing means with a force sufficient to rupture the rupturable sealing means.
2. A syringe apparatus as recited in claim 1, wherein the barrel means comprises a hollow elongated barrel including a sidewall extending between the bottom end and a top grasping end, the sidewall having an interior surface defining a chamber for holding a composition, the chamber having an access opening at the top grasping end of the barrel for accessing the chamber and having a flow opening located at the bottom end of the barrel for enabling the composition held in the chamber to exit the chamber.
3. A syringe apparatus as recited in claim 1, wherein the delivery means comprises a delivery tip having a coupling end opposite a delivery end with a conduit extending there between, the conduit having a conduit inlet located at coupling end and a conduit outlet located at delivery end, the coupling end of the delivery tip being coupled to the bottom end of the barrel so that the conduit inlet is positioned to receive the composition held in the barrel from the flow opening at the bottom end of the barrel.
4. A syringe apparatus as recited in claim 1, wherein the means for rupturable sealing of the composition held within the barrel comprises a self-sealing, stretchable, rupturable membrane.
5. A syringe apparatus as recited in claim 1, wherein the means for rupturable sealing of the composition held within the barrel comprises a self-sealing, stretchable, rupturable membrane held between the barrel means and the delivering means
6. A syringe apparatus as recited in claim 1, wherein the means for rupturable sealing of the composition held within the barrel comprises a self-sealing, stretchable, rupturable membrane held between the barrel means and the delivering means, and wherein the rupturable membrane had a flat shape before being positioned between the barrel means and the delivering means.

7. A syringe apparatus as recited in claim 1, wherein the means for rupturable sealing of the composition held within the barrel comprises a self-sealing, stretchable, rupturable membrane held between the barrel means and the delivering means, and wherein the rupturable membrane had a disc shape before being positioned between the barrel means and the delivering means.

8. A syringe apparatus as recited in claim 1, wherein the means for rupturable sealing of the composition held within the barrel comprises a self-sealing, stretchable, rupturable membrane held between the barrel means and the delivering means, and wherein the rupturable membrane had a preshaped configuration to conform to a portion of the shape of the barrel means before being positioned between the barrel means and the delivering means.

9. A syringe apparatus as recited in claim 1, wherein the means for rupturable sealing of the composition held within the barrel comprises a self-sealing, stretchable, rupturable membrane held between the barrel means and the delivering means, and wherein the rupturable membrane has a preshaped configuration to conform to a portion of the shape of the delivering means before being positioned between the barrel means and the delivering means.

10. A syringe apparatus as recited in claim 1, further comprising plunger means for advancing the composition positioned within the barrel means.

11. A syringe apparatus for dispensing a composition, the syringe apparatus comprising:

(a) a hollow elongated barrel including a sidewall extending between a top grasping end and an opposing bottom end, the sidewall having an interior surface defining a chamber for holding a composition, the chamber having an access opening at the top grasping end of the barrel for accessing the chamber and having a flow opening located at the bottom end of the barrel for enabling the composition held in the chamber to exit the chamber;

(b) a delivery tip having a coupling end opposite a delivery end with a conduit extending there between, the conduit having a conduit inlet located at coupling end and a conduit outlet located at delivery end, the coupling end of the delivery tip being coupled to the bottom end of the barrel so that the conduit inlet is positioned to receive the composition held in the chamber from the flow opening of the chamber at the bottom end of the barrel; and

(c) a rupturable membrane positioned between the coupling end of the delivery tip and the bottom end of the barrel so as to prevent the flow of the composition

held in the chamber out of the flow opening of the chamber and into conduit of the delivery tip via the conduit inlet until pressure is exerted against the composition so that the composition is pushed against the rupturable membrane with a force sufficient to rupture the rupturable membrane.

12. A syringe apparatus as recited in claim 11, wherein the rupturable membrane had a flat shape before being positioned between the coupling end of the delivery tip and the bottom end of the barrel.

13. A syringe apparatus as recited in claim 11, wherein the rupturable membrane had a disc shape before being positioned between the coupling end of the delivery tip and the bottom end of the barrel.

14. A syringe apparatus as recited in claim 11, wherein the rupturable membrane was preshaped to conform to a portion of the bottom end of the barrel before being positioned between the coupling end of the delivery tip and the bottom end of the barrel.

15. A syringe apparatus as recited in claim 11, wherein the rupturable membrane was preshaped to conform to a portion of the coupling end of the delivery tip before being positioned between the coupling end of the delivery tip and the bottom end of the barrel.

16. A syringe apparatus as recited in claim 11, wherein the rupturable membrane is capable of stretching so as to be self-sealing.

17. A syringe apparatus as recited in claim 11, wherein the rupturable membrane is positioned with an adhesive.

18. A syringe apparatus as recited in claim 11, wherein the barrel has an exit tube extending from the bottom end, wherein the barrel has a radial extension extending integrally from the sidewall at the bottom end inward to define an exit port, wherein the exit port is the opening into a channel that extends through the exit tube, wherein the channel terminates at an exit tube outlet which is the flow opening.

19. A syringe apparatus as recited in claim 11, wherein the barrel has an exit tube extending from the bottom end, wherein the barrel has a radial extension extending integrally from the sidewall at the bottom end inward to define an exit port, wherein the exit port is the opening into a channel that extends through the exit tube, wherein the channel terminates at an exit tube outlet which is the flow opening; and

wherein the rupturable membrane is positioned over the exit tube outlet before the rupturable membrane is positioned between the coupling end of the delivery tip and the bottom end of the barrel.

20. A syringe apparatus as recited in claim 11, wherein the barrel has an exit tube extending from the bottom end, wherein the barrel has a radial extension extending integrally from the sidewall at the bottom end inward to define an exit port, wherein the exit port is the opening into a channel that extends through the exit tube, wherein the channel terminates at an exit tube outlet which is the flow opening; and

wherein the rupturable membrane is positioned such that a flat portion of the rupturable membrane stretches over the exit tube outlet and a draped portion of the rupturable membrane stretches down over the exit tube.

21. A syringe apparatus as recited in claim 11, wherein the delivery tip has a top surface at the coupling end that defines the conduit inlet, wherein top surface extends to a flange at the coupling end, and

wherein the rupturable membrane is positioned over the coupling end of the delivery tip and is stretched to drape over the flange.

22. A syringe apparatus as recited in claim 11, wherein the delivery tip has a top surface at the coupling end that defines the conduit inlet,

wherein the barrel has a radial extension extending integrally from the sidewall at the bottom end of the barrel, and

wherein the rupturable membrane is positioned between the top surface of the delivery tip and the radial extension of the barrel.

23. A syringe apparatus as recited in claim 11, further comprising a plunger for advancing the composition positioned within the barrel means, the plunger including a distal lead end opposite from a proximal pushing end with a stem extending between the distal lead end and the proximal pushing end, the plunger distal lead end being inserted into the chamber of the barrel so that the stem of the plunger is in sliding engagement with the chamber.

24. A preloaded syringe apparatus for dispensing a preloaded composition, the syringe apparatus comprising:

(a) a hollow elongated barrel including a sidewall extending between a top grasping end and an opposing bottom end, the sidewall having an interior surface defining a chamber for holding a composition, the chamber having an access opening at the top grasping end of the barrel for accessing the chamber and having a flow opening located at the bottom end of the barrel for enabling the composition held in the chamber to exit the chamber;

(b) a delivery tip having a coupling end opposite a delivery end with a conduit extending there between, the conduit having a conduit inlet located at coupling end and



a conduit outlet located at delivery end, the coupling end of the delivery tip being coupled to the bottom end of the barrel so that conduit inlet is positioned to receive the composition held in the chamber from the flow opening of the chamber at the bottom end of the barrel;

(c) a rupturable membrane positioned between the coupling end of the delivery tip and the bottom end of the barrel so as to prevent the flow of the composition held in the chamber out of the flow opening of the chamber and into the conduit of the delivery tip via the conduit inlet until pressure is exerted against the composition so that the composition is pushed against the rupturable membrane with a force sufficient to rupture the rupturable membrane; and

(d) a plunger positioned within the chamber of the barrel to advance the composition positioned within the barrel through the flow opening of the chamber at the bottom end of the barrel.

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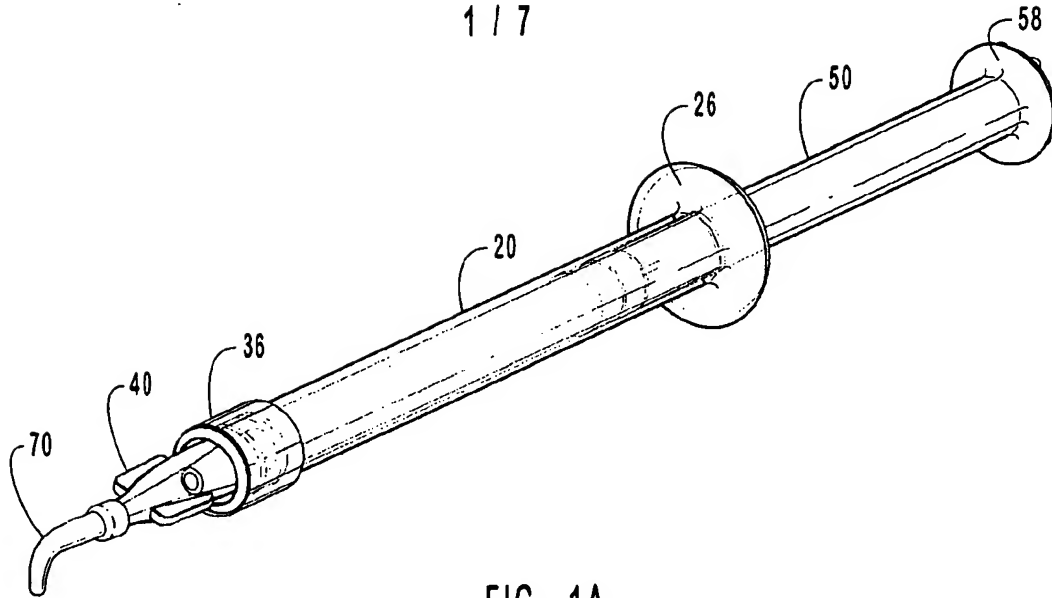


FIG. 1A

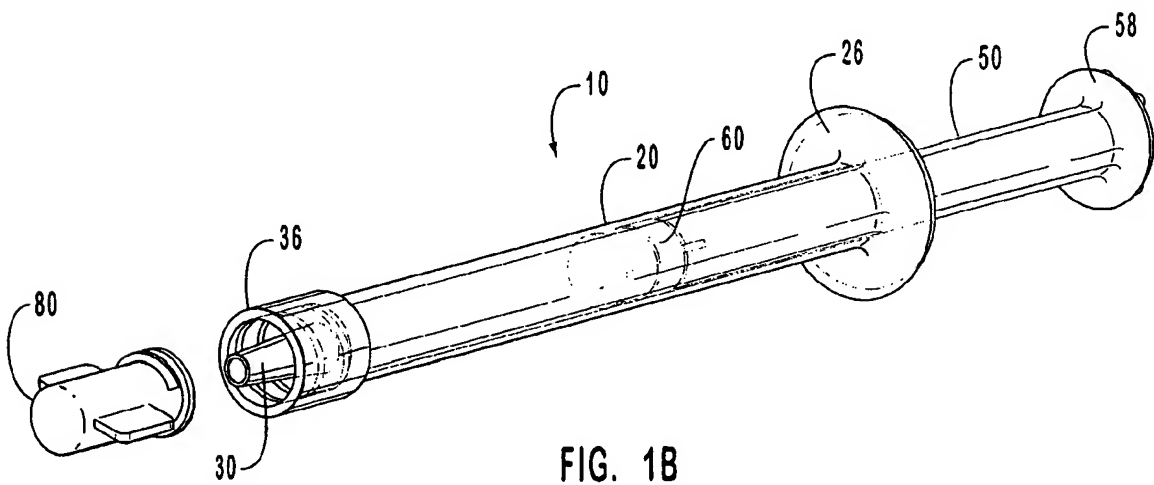


FIG. 1B

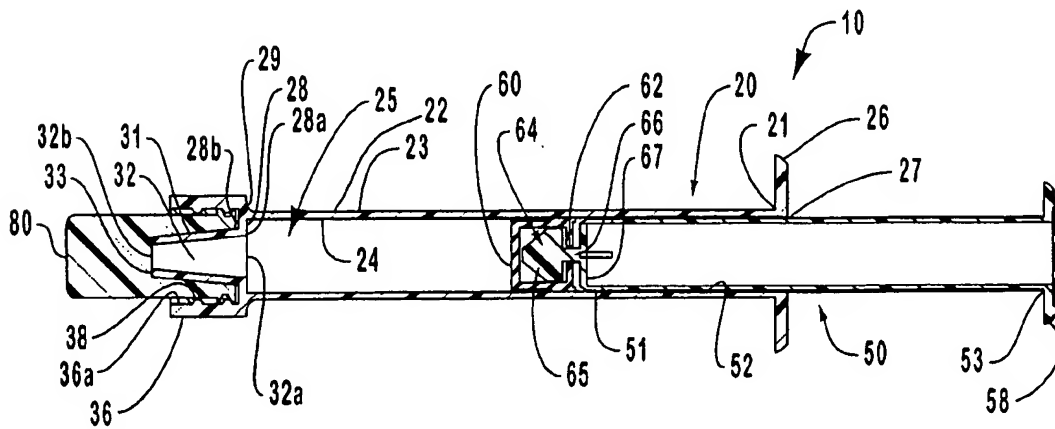


FIG. 1C

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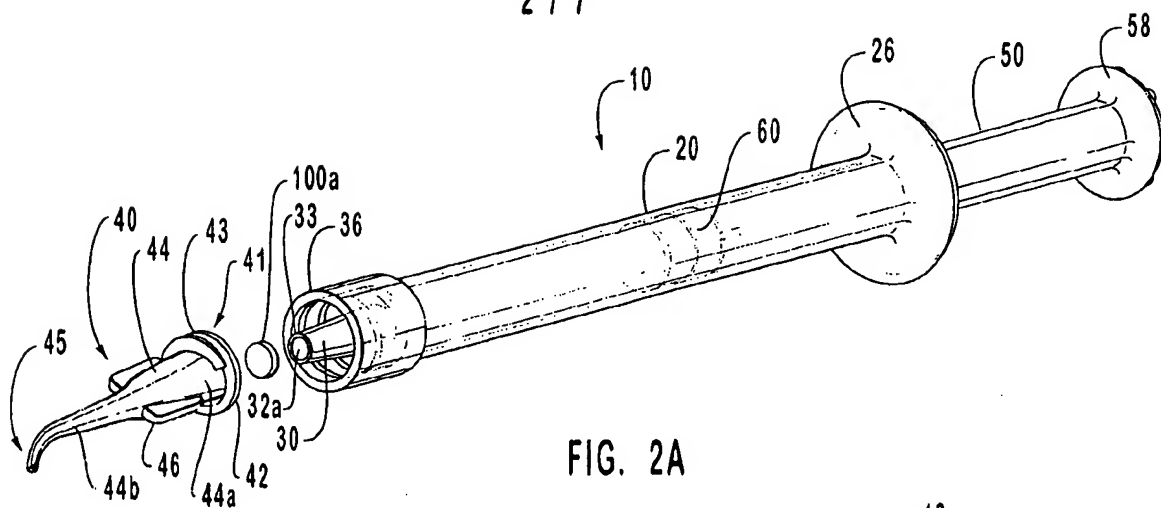


FIG. 2A

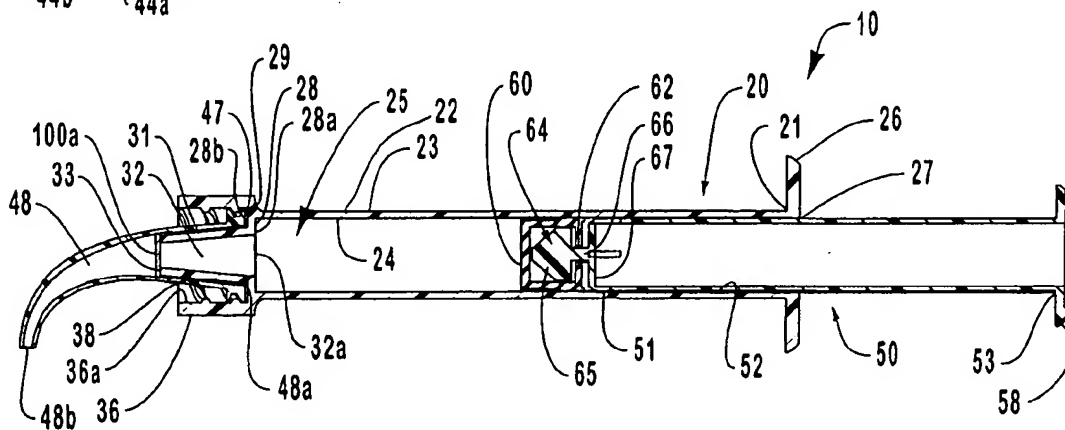


FIG. 2B

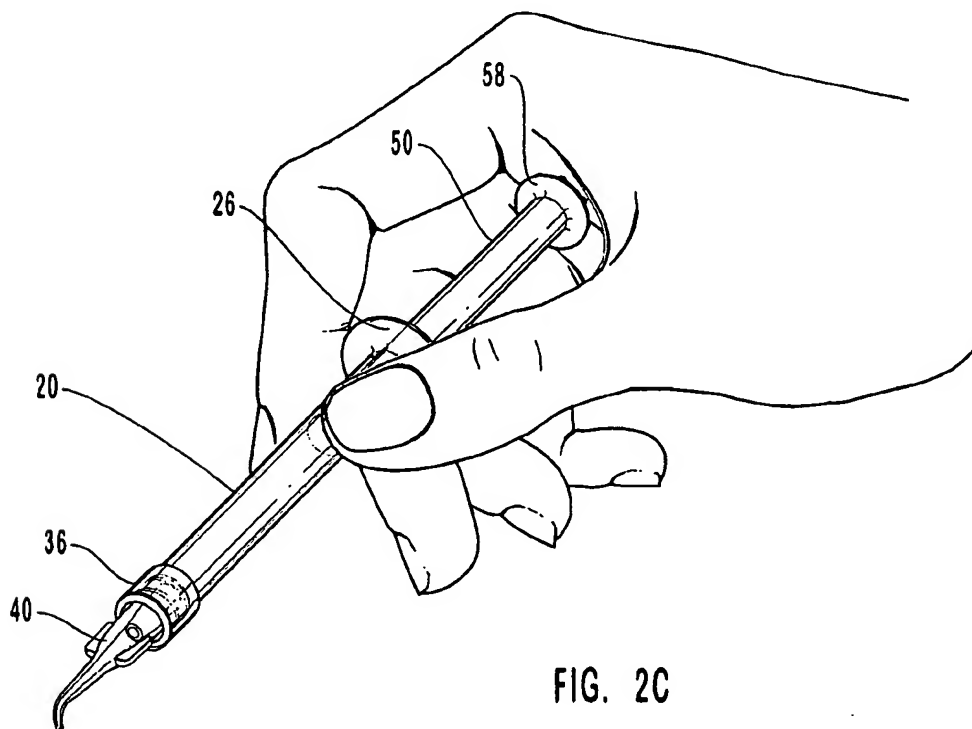
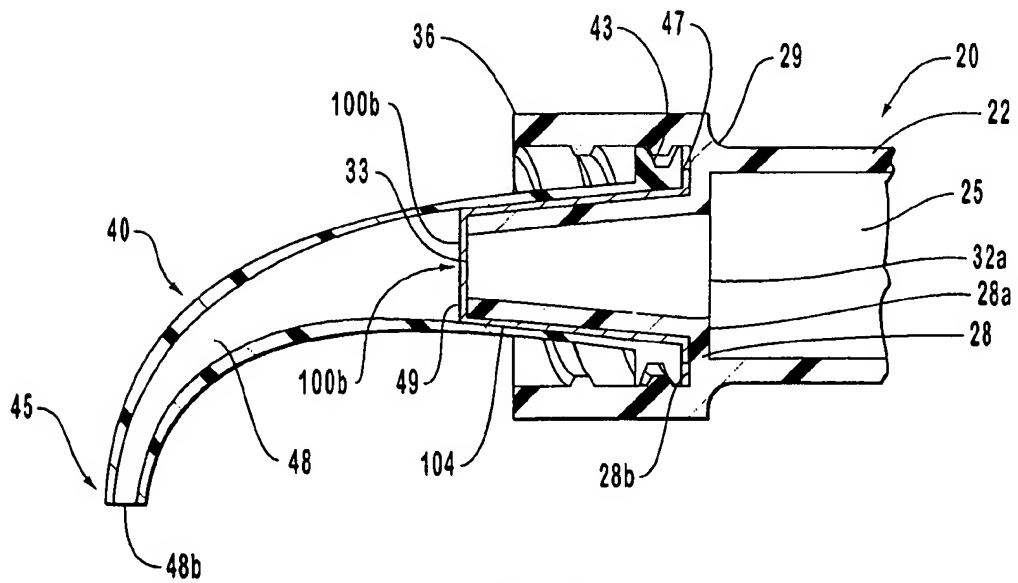
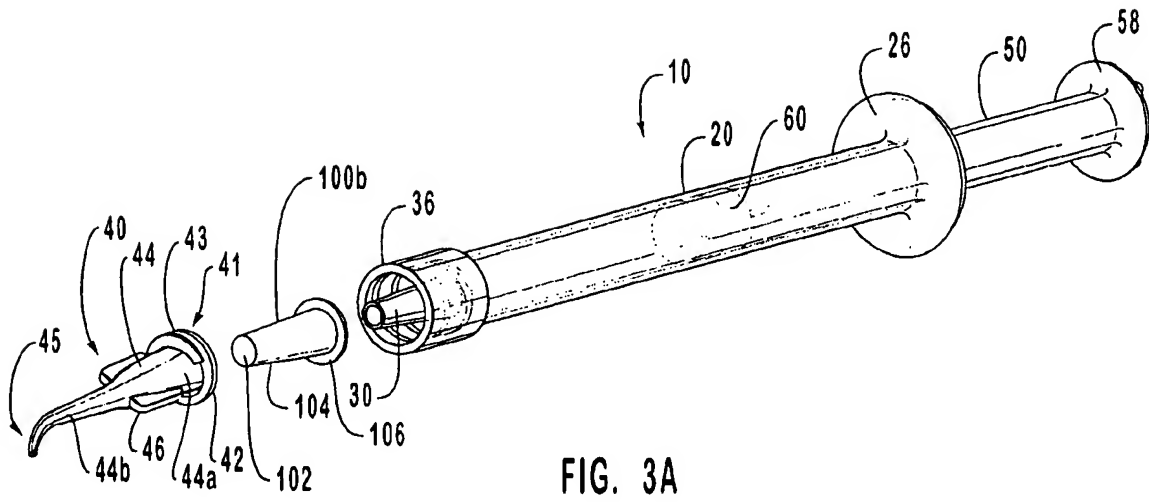


FIG. 2C

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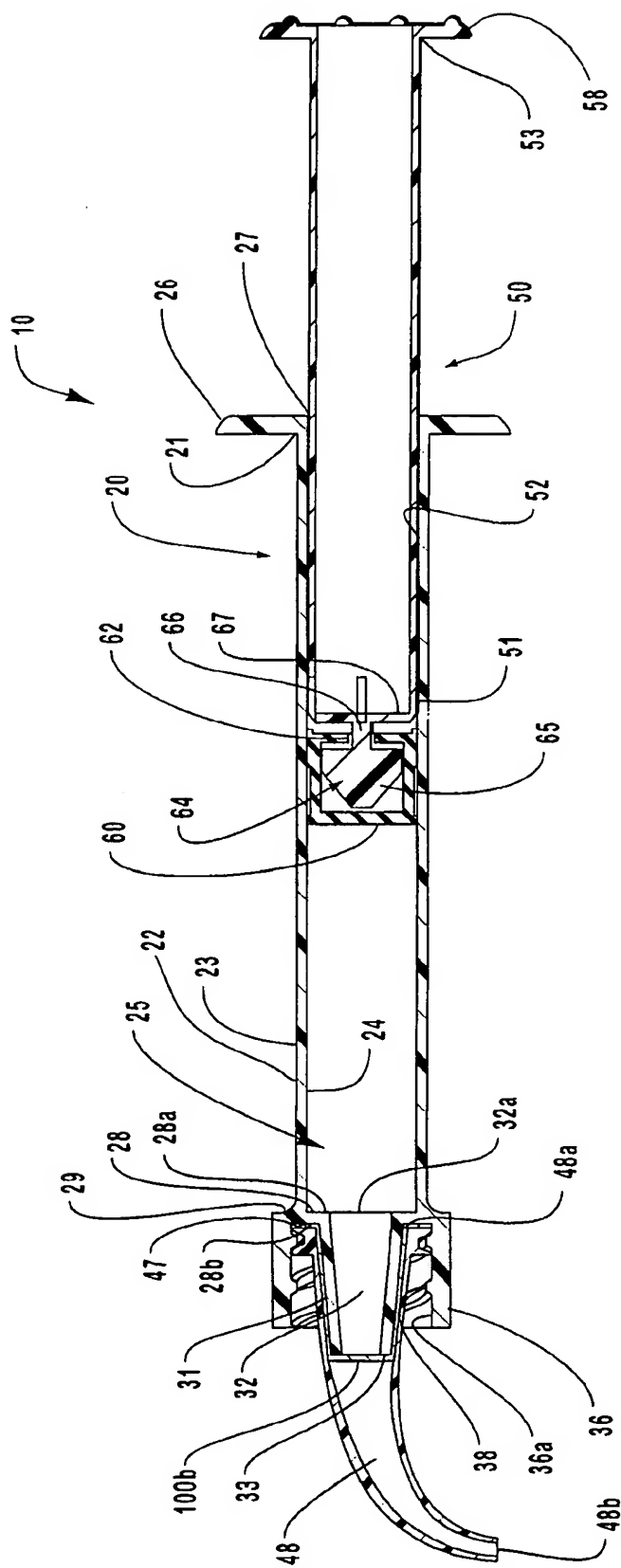


FIG. 3C

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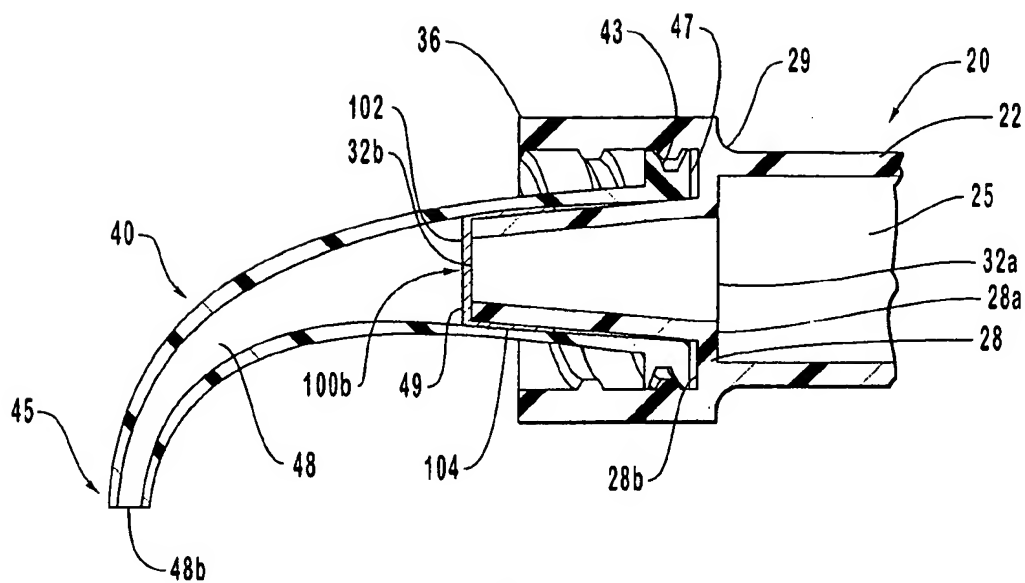


FIG. 3D

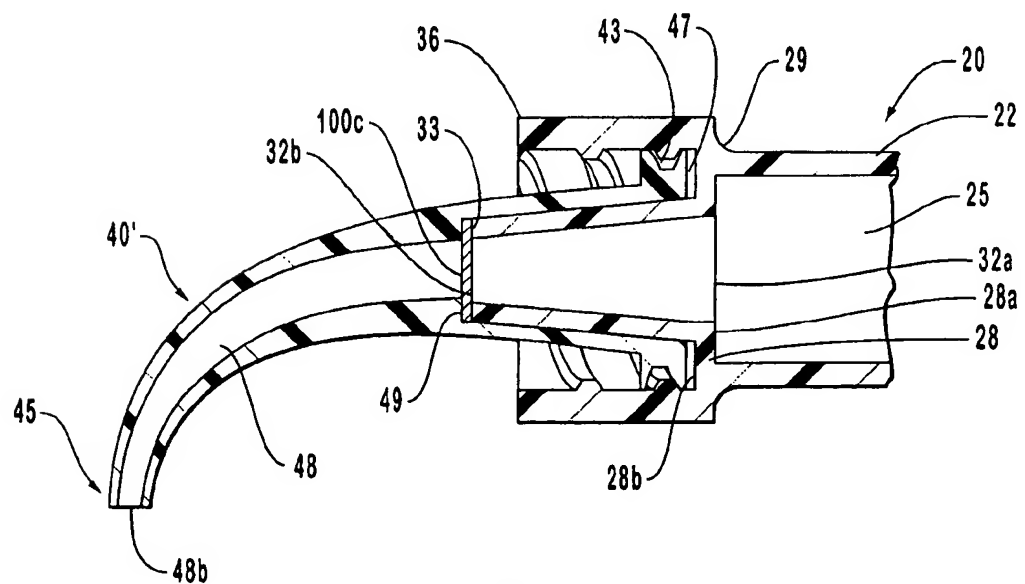


FIG. 4

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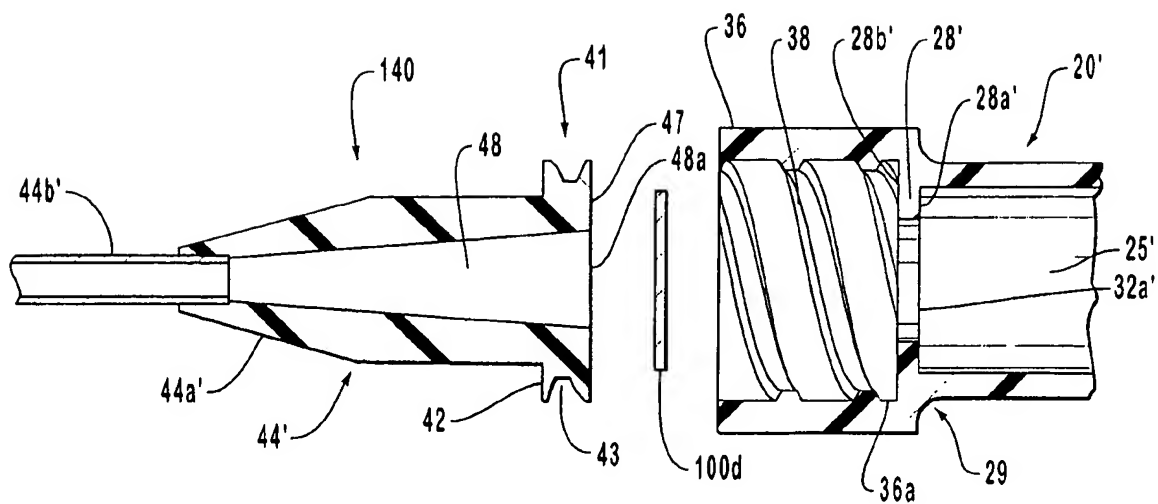


FIG. 5A

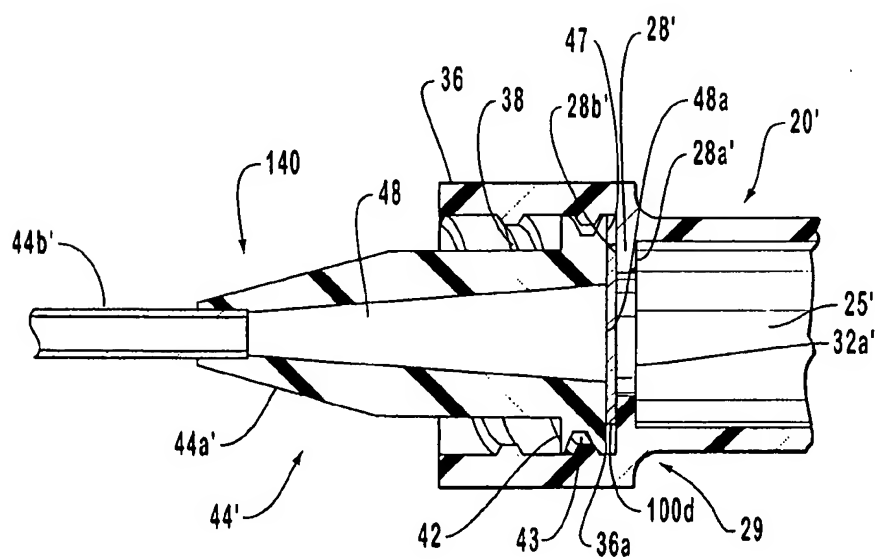


FIG. 5B





## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/05744

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) :A61M 5/24

US CL :604/200

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/199-206, 244

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US 4,331,146 A (BRIGNOLA) 25 May 1982, entire document.	1-16, 18-24 ----- 17
X — Y	US 3,450,135 A (SARNOFF) 17 June 1969, entire document.	1-5, 8-11, 14-16, 18-24 ----- 6-7, 12-13, 17
A	US 4,713,061 A (TARELLO et al) 15 December 1987, figures.	1
A	US 3,391,695 A (SARNOFF) 9 July 1968, figures.	1

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
* "A" document defining the general state of the art which is not considered to be of particular relevance	* "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
* "E" earlier document published on or after the international filing date	* "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
* "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	* "Z" document member of the same patent family
* "O" document referring to an oral disclosure, use, exhibition or other means	
* "P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

18 MAY 2001

Date of mailing of the international search report

28 JUN 2001

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